

REMARKS

The present amendment is responsive to the Official Action mailed January 4, 2007. A petition for a one-month extension of the term for response to said Official Action, to and including May 4, 2007, is transmitted herewith.

Claims 1-12 were pending in the application. In the Office Action mailed January 4, 2007, claims 1-12 have been rejected. In the instant Amendment, claims 1-11 have been amended, and new claims 13-18 have been added. Upon entry of the instant Amendment, claims 1-18 will be pending in the application.

Claim 1 has been amended to recite that the bee venom has a purity as that prepared by a method comprising filtering through a 25 mcm or less filter. Support for the amendment is found in the specification at page 4, paragraph [0010], page 10, paragraph [0024], and page 11, paragraph [0026]. Claim 1 has also been amended to replace the word "compound" with the word "composition."

Claims 2-10 have been amended so that there is appropriate antecedent basis. Claims 6-8 and 11 have been amended to insert a space between each number and the corresponding unit of measure.

Claim 11 has also been amended to recite that the preparation is filtered through a 25 mcm or less filter (emphasis added). Support for amendment is found in the specification at, e.g., page 11, paragraph [0026].

New claims 13-18 have been added. Support for new claim 13 is found in the specification at page 13, paragraphs [0031] and [0032]. Support for new claim 14 is found in the specification at page 4, paragraph [0010], and page 11, paragraph [0026].

Support for new claims 15-18 is found in the specification at, e.g., page 10, paragraph [0023].

No new matter has been added by these amendments. Entry of the foregoing amendments and consideration of the following remarks are respectfully requested.

THE OBJECTION TO THE CLAIMS SHOULD BE WITHDRAWN

Claims 6-8 and 11 have been objected to for lacking spaces between the numbers and the corresponding units of the measure. Applicant has amended the claims to insert spaces between the number and the unit of measure. The objection is therefore obviated and should be withdrawn.

THE REJECTION UNDER 35 U.S.C. § 102 SHOULD BE WITHDRAWN

Claims 1-9 and 11-12 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Steigerwaldt et al., 1966, *Industrial Medicine and Surgery* XXXV:1045-1049 ("Steigerwaldt"). The Examiner contends that Steigerwaldt anticipate the claimed invention because Steigerwaldt teaches bee venom/procaine combinations in which the ratios of procaine and bee venom are 0.2 mg procaine to 0.06 mg, 0.18 mg, 0.54 mg and 1.62 mg bee venom, respectively, i.e., 10:3, 1:0.9, 1:2.7, and 1:8.1, respectively.

Applicant has amended claim 1 to recite that the bee venom has a purity as that prepared by a method comprising filtering through a 25 mcm or less filter. Steigerwaldt does not teach that its bee venom has a purity as that prepared by filtering through a 25 mcm or less filter.

In the Office Action, with respect to claim 11, the Examiner contends that the limitation that the bee venom preparation is filtered through a 25 mcm filter adds no

patentable weight because "the bee[n] venom preparation of Steigerwaldt et al. is for in vivo use and is inherently sterilized and purified for pharmaceutical use" (see, the Office Action last paragraph at page 4). The rejection appears to be based on the Examiner's belief that Steigerwaldt's standard bee venom is inherently the same as the preparation claimed in claim 11 even though Steigerwaldt does not teach filtering. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " See, *Manual of Patent Examining Procedure (MPEP)*, 8<sup>th</sup> Ed., Rev. 5, Aug. 2006, at 2100-47, citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Thus, in order for the Examiner's rejection to stand, Steigerwaldt's bee venom preparation must necessarily be the same as the preparation claimed in claim 11. This is clearly not the case.

Applicant respectfully points out that even assuming, *arguendo*, that the bee venom preparation of Steigerwaldt et al. is sterilized and purified for pharmaceutical use, such a bee venom preparation is not inherently as pure as that produced and used in accordance with the present invention. For example, as is well-known in the art, filtering through a 25 mcm or less filter removes particles larger than the filter grade size from the bee venom preparation. Assuming that Steigerwaldt's bee venom might be sterilized and might be purified, it does not automatically follow that particles of the claimed sizes are removed. Thus, Steigerwaldt's bee venom preparation is not necessarily the same as the preparation claimed in claim 11.

Applicant also respectfully points out that the Examiner fails to provide objective evidence or cogent technical reasoning to support the conclusion of inherency. In addition, there is nothing in the reference to teach purification at all, let alone providing a bee venom as pure as that claimed irrespective of how it is achieved.

Therefore, Applicant respectfully submits that the rejection of claims 1-9 and 11-12 under 35 U.S.C. § 102(b) over Steigerwaldt should be withdrawn.

THE REJECTION UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN

Claims 1-10 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Steigerwaldt in view of Simics, *American Bee Journal*, Feb. 1996, 107-109 ("Simics"). The Examiner contends that although Steigerwaldt does not teach using lidocaine as the local anesthetic, Simics teaches using bee venom with xylocaine or lidocaine. As this rejection would be applied to the claims as amended, Applicant respectfully disagrees with the Examiner for reasons set forth below.

A finding of obviousness under 35 U.S.C. § 103(a) requires a determination that the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. Deere*, 383, U.S. 1 (1966). The relevant inquiry is whether the prior art suggests the invention and whether the prior art provides one of ordinary skill in the art with a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

Applicant respectfully points out that Steigerwaldt fails to provide a person skilled in the art any suggestion or motivation to provide bee venom that has a purity such as that

which could be achieved by filtering through a 25 mcm or less filter. For example, Steigerwaldt does not teach or suggest desirability or advantages of bee venom preparation in which particles larger than the filter grade size have been removed. Simics merely teaches that bee venom can be used in conjunction with lidocaine. Simics does not teach or suggest anything about the characteristics of the bee venom itself, including the combination in a single product or a level of purity. Thus, Simics does not provide what are missing in Steigerwaldt.

Therefore, Applicant respectfully submits that the rejection of claims 1-10 under 35 U.S.C. § 103(a) over Steigerwaldt in view of Simics should be withdrawn.

As it is believed that all of the objection and rejections set forth in the Office Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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